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General Comment

The Society of Interventional Radiology (SIR), a physician association comprised of over 6,100 members representing the majority of practicing vascular and interventional radiologists in the United States, appreciates the opportunity to comment on the proposed revisions to the Licensing Guidance for Yttrium-90 Microspheres. The SIR strongly opposes proposed changes to the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" that would eliminate vendor involvement from the Interventional Radiology pathway to Authorized User (AU) status.

The current process, also known as Pathway 2, has been in place since the concept evolved that Interventional Radiologists are the natural AU's of these devices. For the procedure, Interventional Radiologists:

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-Perform the dosimetry necessary to deliver the appropriate activity to the patient
-Oversee and ensure appropriate handling and preparation of the Yttrium-90 (Y90) devices
-Directly deliver the therapy to the patient
-Are primarily responsible for longitudinal care of the patient following the procedure.

Collaboration between physicians and industry helps ensure safe and comprehensive training in the use of the Y90 devices to improve care of patients dying from cancer.

The existing guidelines have been tremendously successful in expanding the number of users of the Y90 devices while maintaining impeccable safety. This has resulted in many tens of thousands of cancer patients globally who have safely received Y90 treatment for their liver malignancies. Manufacturer And User facility Device Experience (MAUDE) reports have remained 10/year for both devices since 2013. The majority of the MAUDE reports focus on procedural complication and treatment toxicities seen with all types of hepatic embolization, not specific to the Y90 devices. It is statistically implausible for reduced vendor involvement to result in a measurable improvement in safety.

Proposed changes to the current arrangement, in which physicians and industry work closely together to ensure the appropriate training of interventional radiologists in the safe use of these devices will make it exceedingly difficult for Interventional Radiologists developing a clinical practice in radioembolization. Without the current direct training provided offsite by the device vendors, physician training will have to be solely performed by direct proctoring. Securing physician proctors is a challenge; physicians have limited time and availability away from their own clinical practices. Placing additional responsibilities on physician proctors may also have the untoward effect of limiting access to care, particularly for programs in underserved areas. The unanticipated consequence of the proposed changes is that training Interventional Radiologists in the safe and effective use of these devices will suffer greatly and patients dying from cancer will have diminished access to this palliative therapy.

In summary, Interventional Radiologists deliver high quality minimally invasive care via imaging guidance, employing a variety of technologies. Training with other devices, such as aortic stent grafts, frequently involves a combination of vendor and physician collaboration. The existing NRC guidelines have facilitated training Interventional Radiologists in the safe and effective use of the Y90 devices, benefiting patients, physicians, and the government. There is no evidence of a need for change to the current NRC guidelines.

Once again, the SIR appreciates the opportunity to provide these comments on the proposed revisions.

Sincerely,

Suresh Vedantham, MD, FSIR
SIR President 2017-2018